K113469

NIPRO MEDICAL CORPORATION

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OCT 18 2012

510(k) Summary – Nipro Huber Needle

(21 CFR 807.92)

1. **Submitter:** Nipro Medical Corporation
   FDA Registration No: 1056186

   Contact Person: Jessica Oswald
   Prepared on: 29 June 2012

2. **Trade Name:** NIPRO Huber Needle

   Common Name: Huber Needle

   Classification Name: Needle, Hypodermic, Single Lumen

   Classification Code: FMI (per 21 CFR 880.5570)
   Class II

3. **Predicate Device:** **EXEL** Huber Needle (K895769)

4. **Device Description:**
   This device consists of a cannula affixed to a hub with a needle cap. Both straight and 90° angled types are available.

5. **Indication for Use:**

   This device is intended for administration of drug solutions, or blood sampling into or from a Reservoir implanted in the body.

6. **Technological Characteristics**

   The basic structure of the device consists of a needle, needle hub and needle cap. The needle is either bent at a 90° angle and is available in gauges 19, 20 and 22 and in lengths of ¾ " - 1 ½" or straight type and is available in gauges 19, 20 and 22 and in lengths 1" – 1 ½ ".

7. Performance Testing

Testing of the NIPRO Huber Needle was completed in conformance with the following standards:

Reference Number	Standard Title
ISO 8536-4:2010	Infusion equipment for medical use, Part 4: Infusion sets for single use, gravity feed
ISO 10555-3:1996	Sterile single use catheters, Part 3: central venous catheters
ISO 7864:1993	Sterile hypodermic needles for single use
ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1:General requirements
ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Test for In Vitro Cytotoxicity
ISO 10993-4:2002	Biological Evaluation of Medical Devices – Selection of Test for Interaction with Blood
ISO 10993-10:2002	Biological Evaluation of Medical Devices – Test for Irritation and Delayed-Type Hypersensitivity
ISO 10993-11:2006	Biological Evaluation of Medical Devices – Test for Systemic Toxicity
IAEA-TECDOC-539	Guidelines for Industrial Radiation Sterilization of Disposable Medical Products (Cobalt-60 Gamma Irradiation)
USP 31	<151> Pyrogen Test (USP Rabbit Test)
USP 31	<161> Transfusion and Infusion Assemblies and Similar Medical Devices

NIPRO Huber Needle successfully met the requirements for these standards.
In addition, it met or exceeded the acceptance criteria for the following performance tests:

Performance Tests	Specification
Stiffness Test	Must conform to ISO 9626 (SU = 0.55 mm)
Bending Breakage Resistance Test	Must conform to ISO 9626 (Shall not break)
Elasticity	Must conform to JIS T 3209 (Shall go back to the original position)
Bending Strength	Must conform to JIS T 3209 (Shall not break)
Corrosive Resistance	Must conform to ISO 9626 (No corrosion shall be allowed)
Cannula Dirt Test	Must conform to the internal test (No dirt shall be allowed)
Coring Test	Must conform to FDA Coring Test Method (No coring shall occur

Performance Tests	Specification
Cannula/Hub adhesive strength measurement	19G: ≥ 69 N 20G: ≥ 54 N 22G: ≥ 34 N
Popping needle tip inspection	No sound of puncture popping noise.
Test for particulate matter	Contamination Index I= Na - Nb 90
Transportation Testing	Withstand distribution environment

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8. Substantial Equivalence

The NIPRO Huber Needle are identical in physical properties, materials, configurations and having the same intended use as the predicate device (i.e., the original EXEL Huber Needle [K895769]). Although the manufacturing process for the needle bevel has been modified, performance testing shows that the performance of the new NIPRO Huber Needle is similar in most performance test and is significantly better in the Coring Test. Therefore, no new issues of safety or effectiveness are introduced by these changes.

Specification	NIPRO Huber Needle		Predicate EXEL Huber Needle	
Physical and Material				
Needle	**Components**	**Materials**	**Components**	**Materials**
	Cannula	Stainless Steel	Cannula	Stainless Steel
	Hub	PP	Hub	PP
	Needle Cap (Bent Needle)	PVC	Needle Tube Cap	PVC
	Needle Cap (Straight Needle)	PP	Needle Cap (Straight Needle)	PP
Instructions for Use	Same		Same	
Operational				
Device Type	Standard non-coring Huber needle		Same	
Biological	Biocompatibility tests were performed according to ISO 10993 Parts 4, 5, 10 and 11 as a prolonged duration, indirect blood path contacting device.		Same	
Sterilization Method	Ethylene oxide		Same	

PVC:polyvinyl chloride
PP: polypropylene

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2012

Nipro Medical Corporation
Ms. Jessica Oswald-McLeod
Regulatory Affairs
3150 North West 107TH Avenue
Miami, Florida 33172

Re: K113469
Trade/Device Name: Nipro Huber Needle/EXEL Huber Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 10, 2012
Received: October 11, 2012

Dear Ms. Oswald-McLeod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113469

Device Name: NIPRO Huber Needle/EXEL Huber Needle

Indications for Use:

This device is intended for administration of drug solutions, or blood sampling into or from a Reservoir implanted in the body.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/17/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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